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EG&G - ROCKY FLATS PLANT
ENVIRONMENTAL MANAGEMENT

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**ROCKY FLATS PLANT
EMD ADMINISTRATION
PROCEDURES MANUAL**

CATEGORY 1

Manual No.: 3-21000-ADM
Procedure No.: Table of Contents, Rev 3
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ADMIN RECORD

A-SW-001042

REVIEWED FOR CLASSIFICATION/UCM

By *George H. Setlock*

Date *4/30/92*

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Approved By:

TITLE:
CORRECTIVE ACTION

[Signature]

4/8/92

Director DATE
Environmental Management

1.0 PURPOSE

To establish a system for promptly identifying, determining the root cause, and providing corrective action for significant or recurring conditions adverse to quality, or potentially adverse to quality. These conditions may include, but are not limited to, a breakdown of the Rocky Flats Plant (RFP) Environmental Management (EM) QA Program and/or repetitive nonconformances.

2.0 SCOPE

This procedure applies to significant or recurring conditions adverse to quality, which can only be corrected through management intervention, as determined by the Department Director or the QAPM.

3.0 DEFINITIONS

- 3.1 Condition Adverse to Quality** - An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. A significant condition adverse to quality is one which, if not corrected, could have a serious effect on safety or effective implementation of the RFP EM Program.
- 3.2 Corrective Action** - Measures taken to rectify conditions that are adverse to quality and, where necessary, to preclude recurrence.

4.0 RESPONSIBILITIES

- 4.1** EM personnel and EM subcontractor personnel assigned to a quality affecting project or task are responsible for identifying any significant or recurring conditions adverse to quality to the QAPM and/or the EMD Director, and for initiating a Nonconformance Report (NCR), if

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appropriate. EM personnel and EM subcontractor personnel are also responsible for implementing assigned corrective actions.

- 4.2 The EM Department Director, or delegate, is responsible for assigning corrective action responsibility to EM and EM subcontractor personnel if the action involves technical activities.
- 4.3 The Quality Assurance Program Manager (QAPM), or delegate, is responsible for assigning corrective action responsibility to QA personnel, as necessary, and is responsible for corrective action verification.

5.0 PROCEDURE

NOTE

If the space in Attachment 1 is not sufficient to complete the documentation, attach additional sheets. Record the EMD CAR No., the Date, and Page of data on any additional sheets.

5.1 Preparation of a Corrective Action Report

- 5.1.1 If the EMD Director or the QAPM identify a condition adverse to quality, or potentially adverse to quality, they shall initiate a corrective action report (Attachment 1). If the Director determines that immediate actions are necessary, the QAPM and affected technical management shall be informed and the actions implemented.
 - 5.1.1.1 The originator shall complete the header and origination sections of a CAR (see Attachments 1 and 2).
 - 5.1.1.2 All CARs shall be assigned a unique number in the following format: RFP-EM-CAR-XX-YY, where XX is the fiscal year and YY is a unique, sequential number starting with 01. CAR numbers are assigned by the EM QAPM, and the numbers are tracked in a deficiency document tracking system in accordance with EMD procedure addressing trend

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analyses. Until the trend analysis procedure is addressed the QAPM shall establish these numbers.

5.1.1.3 The originator shall also prepare NCRs, unless they already exist (see 3-21000-ADM-15.01, Control of Nonconforming Items).

5.1.2 The QAPM and/or the EMD Department Director review and approve the CAR and then directs its entry into a deficiency document tracking system.

5.1.2.1 If the QAPM determines that the immediate remedial actions identified are inadequate to mitigate the adverse condition, the QAPM shall immediately contact appropriate management to ensure the necessary actions are taken in a timely manner.

5.1.2.2 A copy of the CAR submitted shall be sent to the EMD records center (see 3-21000-ADM-17.01, Records Management).

5.1.2.3 The QAPM investigates and then reviews the proposed CAR and revises as necessary if the deficiency identified justifies issuance of a CAR. The QAPM then approves the CAR.

5.1.2.4 If the QAPM determines that a CAR is not appropriate, the QAPM documents this on the CAR but does not approve it.

5.1.2.5 The QAPM sends copies of the CAR to the originator (if known), EMD Director, and the EMD records center (see 3-21000-ADM-17.01, Records Management).

5.1.3 The QAPM shall assign a response date based on the immediacy of the situation but not to

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exceed 30 days from the initiation date of the CAR. The CAR shall be forwarded to responsible management. Responsible management shall identify the cause and propose appropriate remedial/investigative actions to prevent recurrence or provide a plan describing future actions to resolve the CAR. Responsible management shall sign and date the CAR.

5.1.4 The CAR shall then be returned to the QAPM for review of the cause statement and the proposed corrective action.

5.1.5 If the QAPM determines the response is unacceptable, the QAPM shall return a copy of the CAR to the responsible manager indicating it is either rejected or requires amendment (CAR item 15). This action will include a memo addressing the basis for not accepting the CAR and recommendations for revision. The Response Due Date shall be revised as appropriate by the QAPM.

5.1.5.1 Upon receipt of a CAR that requires amendment or has been rejected, the responsible manager shall revise the CAR as appropriate and then return it to the QAPM per Step 5.1.4.

5.1.5.2 The documentation generated in Step 5.1.5 are QA records and shall be handled per 3-21000-ADM-17.01, Records Management.

5.1.6 After the QAPM's approval of the proposed corrective action and determination of cause, the CAR shall be distributed to a responsible manager. Responsible managers shall notify affected personnel at all levels of the adverse condition(s) regarding lessons to be learned to improve conditions or ways to avoid similar occurrences. Also, the responsible managers shall assign a Corrective Action Implementor to carry out the approved corrective actions.

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- 5.1.7 The designated Corrective Action Implementor, upon receipt of the CAR, shall ensure the QAPM's signed approval of the proposed corrective action prior to implementing the corrective action. The Corrective Action Implementor shall complete the corrective action within the schedule established by the QAPM in consultation with the responsible manager and the EMD Director.
- 5.1.8 If, during the course of implementing the corrective actions, the Corrective Action Implementor discovers that the original response to the CAR was in error or not of sufficient detail, an amended response shall be submitted to the QAPM detailing the new information and projecting the subsequent revised due date.
- 5.1.9 If the required actions cannot be completed by the scheduled due date, an extension request shall be submitted to the QAPM.
- 5.1.9.1 Extension requests shall be evaluated by the Director or delegate, and the results shall be documented and filed with the Corrective Action Report.
- 5.1.9.2 The organization requesting extensions shall be notified of extension requests that are approved or denied.
- 5.1.10 After the corrective action has been completed, the CAR shall be signed and dated by the Corrective Action Implementor (CAR item 14).

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- 5.1.11 The CAR shall be returned to the QAPM for verification of completed corrective action and closure of the CAR. This verification shall ensure that applicable actions have been reviewed, implemented, monitored, and revised, if necessary.
 - 5.1.11.1 Verify completion of the corrective action using audit, surveillance, inspections, or management review of the affected activity.
 - 5.1.11.2 If verification of corrective action is unsatisfactory, reissue the CAR in accordance with Step 5.3.1.
 - 5.1.11.3 Document verification of the corrective actions on the CAR form.
 - 5.1.12 To close the CAR, the QAPM shall:
 - 5.1.12.1 Review the CAR for completeness and effectiveness of corrective action.
 - 5.1.12.2 If Step 5.1.12.1 is satisfactory, then sign and date the report (in the Verification section [see CAR item 18] of the Evaluation block) and record the date of Closure.
 - 5.1.12.3 If the CAR is closed, distribute, log and file the report as a QA Record in accordance with 3-21000-ADM, 17.01, Records Management.
- NOTE**
- The distribution for a closed CAR is the EM Department Director and EM Division Managers.**
- 5.1.12.4 If Step 5.1.11.2 is not satisfactory, issue a memo to the responsible manager to document outstanding concerns and potential resolutions, with a copy to the EMD Director.

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5.2 Failure To Meet Implementation Schedule

5.2.1 If the responsible manager fails to meet the required implementation schedule, as adjusted by approved extension requests, the QAPM shall evaluate the impact on data quality and completeness; and any impacts on health, safety, and the environment. The QAPM should consult with the responsible manager and appropriate health, safety, and environment personnel in preparing this evaluation. The QAPM shall present the evaluation to the EMD Director.

5.2.2 Distribution of this evaluation shall include the responsible manager and the Manager of Rocky Flats Plant Quality Assurance.

5.3 CAR Status Tracking

5.3.1 The CAR (based on the CAR number as described in Step 5.1.1.2) shall be entered into the QA Tracking System. This tracking system shall be used to monitor trends and completion of corrective actions.

5.3.2 The unapproved CARs shall be included in the tracking system for use in 3-21000-ADM-18.04, Trending Analyses. No actions or schedule requirements shall be associated with these unapproved CARs. They shall be treated as if they are closed, and shall have less significance in 3-21000-ADM-18.04, Trending Analyses.

5.3.3 When repetitive or recurring corrective actions are identified, trending analysis shall determine whether further programmatic corrective action is warranted. Subsequent corrective action shall be the subject of a new separate CAR.

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6.0 REFERENCES

- RFP-EM Quality Assurance Program Description
- 3-21000-ADM-15.01, Control of Nonconforming Items
- 3-21000-ADM-17.01, Records Management
- 3-21000-ADM-18.04, Trending Analysis

7.0 ATTACHMENTS

Attachment 1: EM Project Corrective Action Report Form
Attachment 2: Instructions For Completing CAR


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ATTACHMENT 1 EM PROJECT CORRECTIVE ACTION REPORT FORM

 EG&G ROCKY FLATS ENVIRONMENTAL MANAGEMENT DEPARTMENT		EM CAR No. _____		Date _____
		Audit/Surv. No. _____		Page _____ of _____
		Responsible Organization _____		
		Responsible Manager _____		
		Project Name _____		
ORIGINATOR	Personnel Contacted _____			
	Requirement: _____			
	Deficiency (Description): _____			
	Discussion and Recommended Action(s): _____			
	Originator Name: _____		Originator Signature: _____	
RESPONSE	QAPM Name: _____		QAPM Signature/Date: _____	
	Response Due Date: _____			
	Cause: _____			
	Remedial/Investigative Action(s): _____			
	Action(s) to Prevent Recurrence _____			
	<div style="position: relative; width: 100%; height: 100%;"> <div style="position: absolute; top: 50%; left: 50%; transform: translate(-50%, -50%) rotate(-45deg); font-size: 100px; opacity: 0.5;">SAMPLE</div> </div>			
	Response By: _____ Signature _____ Date _____			
	Approved By (Mgr): _____ Signature _____ Date _____			
	RESPONSE ____ Accept ____ Amend ____ Reject		ATL/STL/Date _____	
	QAPM/Date _____			
EVALUATION	CORRECTIVE ACTIONS COMPLETED			
	Implementor Signature/Date _____			
	AMENDED RESPONSE ____ Accept ____ Reject		ATL/STL/Date _____	
	QAPM/Date _____			
	VERIFICATION ____ Satisfactory ____ Unsatisfactory		REMARKS _____	
REF. AUDIT/SURVEILLANCE NO. _____		ATL/STL/Date _____		
QAPM/Date _____				
DATE OF CAR CLOSURE _____				

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ATTACHMENT 2

INSTRUCTIONS FOR COMPLETING CAR

BLOCK/ ITEM NO.	RESPONSIBILITY	INSTRUCTION
<u>Origination:</u>		
Header	Originator/ QAPM	Enter assigned CAR number and date. Enter audit/surveillance number, if applicable. Enter the Responsible Organization, Responsible Manager, and Project Name, if known.
1	Originator/ QAPM	Identify any individuals contacted.
2	Originator/ QAPM	Identify the applicable requirements being addressed.
3	Originator/ QAPM	Describe the deficiency in clear, concise terms. Identify specific information relative to condition such as title, numbers, locations, identification, etc.
4	Originator/ QAPM	Record additional discussion and recommended actions.
5	Originator	Originator prints name and then signs form or records "NA" in both spaces.
6	QAPM	If this is a valid CAR, revises above information as necessary, then signs and dates the CAR.
7	QAPM	Enter response due date.
<u>Response:</u>		
8	Responsible Actionee	Identify root cause of deficiency.
9	Responsible Actionee	Specifies remedial/investigative action(s).
10	Responsible Actionee	List date(s) for accomplishing action.
11	Responsible Actionee	Specify actions needed to prevent/preclude deficiency from occurring in the future.

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ATTACHMENT 2 - (continued) INSTRUCTIONS - continued

- | | | |
|--------------------|-------------------------------------|---|
| 12 | Responsible
Actionee | List date(s) for accomplishing action. |
| 13 | Responsible
Actionee | Enter name, signature, and date. |
| 14 | Responsible
Management | Enter name, signature, and date of the responsible manager. |
| <u>Evaluation:</u> | | |
| 15 | QAPM (ATL/STL) | Indicate results of evaluation of response, sign and date. |
| 16 | Corrective
Action
Implementor | Sign and date when corrective actions are complete. |
| 17 | QAPM | Indicate results of evaluation of any amended response, sign and date. |
| 18a. | QAPM | Indicate results of verification of CAR actions, reference audit/surveillance conducted, sign and date. |
| 18b. | QAPM | Note any pertinent remarks, such as continuation, other documents, etc. |
| 19 | QAPM (ATL/STL) | Reference applicable audit and surveillance, if any. |

Close-Out:

- | | | |
|----|------|------------------------|
| 20 | QAPM | Enter date CAR closed. |
|----|------|------------------------|